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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/632,711 | 08/01/2003 | Dennis A. Carson | 023070-124010US | 2786 |

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EXAMINER

GRAFFEO, MICHELLE

ART UNIT PAPER NUMBER

1614

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/632,711

Applicant(s)

CARSON ET AL.

Examiner

Michelle Graffeo

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-62 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8,14-17, 21-26, 35-38 and 51-58 drawn to a method of treating cancer comprising an IMPDH inhibitor and an agent that inhibits a cellular process regulated by GTP or ATP, classified in class 514, subclass 724.
- II. Claims 9-13,18-20,31-34 and 39-50 drawn to a composition for treating cancer comprising an IMPDH inhibitor and an agent that inhibits a cellular process regulated by GTP or ATP, classified in class 514, subclass 724.
- III. Claims 27-30, drawn to a method for treating cancer wherein the cancer comprises a population of cells deficient in the enzyme MTAP comprising an IMPDH inhibitor, classified in class 514, subclass 385.
- IV. Claims 59-62, drawn to a method of treating an immune system condition, classified in class 514, subclass 724.

Inventions I and II are related as process of use and product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the method of treating cancer can be practiced with a different anticancer agent, for example vincristine which is a microtubule inhibitor. Additionally, the compound product can be used in a

Art Unit: 1614

materially different process, for example for the treatment of immune system disorders (see Simmons W D; Rayhill S C; Sollinger H W. Preliminary risk-benefit assessment of mycophenolate mofetil in transplant rejection. Drug safety: an international journal of medical toxicology and drug experience, (1997 Aug) 17 (2) 75-92.).

Inventions III and I are distinct and capable of separate manufacture, use, and/or sale as claimed. In the instant case, Groups I and III are manufactured separately since Group III does not require the particulars of Group I as claimed because Group III does not require an agent that inhibits a cellular process regulated by GTP or ATP. Group III has separate utility such as treating cancer comprising a population of cells deficient in the enzyme MTAP and therefore will be used to treat a different population.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together. Specifically, treating a disorder of the immune system will require different patient populations (a patient population having a disorder of the immune system) and have different effects than a process of treating cancer (i.e. either the cancer will be treated or the immune condition will be treated).

Inventions III and II are related as process of use and product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the method of treating cancer can be practiced with a different anticancer agent, for example vincristine which is a microtubule inhibitor. Additionally, the compound product can be used in a materially different process, for example for the treatment of immune system disorders (see Simmons W D; Rayhill S C; Sollinger H W. Preliminary risk-benefit assessment of mycophenolate mofetil in transplant rejection. Drug safety: an international journal of medical toxicology and drug experience, (1997 Aug) 17 (2) 75-92.).

Inventions IV and II are related as process of use and product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the method of treating an immune system condition can be practiced with a different agent, for example cyclosporine. Additionally, the compound product can be used in a materially different process, for example for the treatment of immune system disorders (see Simmons W D; Rayhill S C; Sollinger H W. Preliminary risk-benefit assessment of

mycophenolate mofetil in transplant rejection. Drug safety: an international journal of medical toxicology and drug experience, (1997 Aug) 17 (2) 75-92.).

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together. Specifically, treating a disorder of the immune system will require different patient populations (a patient population having a disorder of the immune system) and have different effects than a process of treating cancer (i.e. either the cancer will be treated or the immune condition will be treated).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and/or separate classification, restriction for examination purposes as indicated is proper.

A telephone call was made to Beth Kelly on August 19, 2005 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

22 August 2005
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